

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff,

v.

DAKOCYTOMATION CALIFORNIA INC.,

Defendant.

Civil Action No. 04-1522-GMS

**PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

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TABLE OF ABBREVIATIONS

Ventana	Plaintiff Ventana Medical Systems, Inc.
Dako	Defendant DakoCytomation California Inc.
'901 patent	U.S. Patent No. 6,827,901, the patent-in-suit
Artisan	The accused Artisan Staining System
<hr/>	
Dako Br.	Defendant's Memorandum in Support of its Motion for Summary Judgment of Noninfringement (Mar. 16, 2006) (D.I. 89)
Zeliger Ex.	The indicated exhibit to the Declaration of Michael E. Zeliger in Support of Defendant's Motion for Summary Judgment of Noninfringement (Mar. 16, 2006) (D.I. 90)
Chang Ex.	The indicated exhibit to the Declaration of Peter H. Chang in Support of Plaintiff's Answering Brief in Opposition to Defendant's Motion for Summary Judgment, filed concurrently herewith
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Glezer Report	Expert Report of Dr. Ari Glezer, attached as Zeliger Ex. 4
Leon Decl.	Declaration of Scott Leon in Support of Defendant's Motion for Summary Judgment of Noninfringement (Mar. 16, 2006) (D.I. 91)
Manion Report	Expert Report of William L. Manion, attached as Chang Ex. 3
Sharon Decl.	Declaration of Andre Sharon, Ph.D. in Support of Plaintiff's Answering Brief in Opposition to Defendant's Motion for Summary Judgment, filed concurrently herewith
Sharon Report	Expert Report of Andre Sharon, Ph.D., attached as Sharon Decl. Ex. 1

I. NATURE AND STAGE OF THE PROCEEDING

Ventana is a leading manufacturer of automated slide staining equipment and the owner of the '901 patent. Dako manufactures the Artisan. Ventana asserts that Dako infringes claims 1, 2, 3 and 45 of the '901 patent by making, using, offering to sell and selling the Artisan. Claims 1 and 45 are the independent claims of the '901 patent.

Dako's summary judgment motion is based solely on the "air mixer" element of claims 1 and 45:

an air mixer comprising an air jet and an air supply means positioned adjacent to [a] said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

Chang Ex. 1 at 25:14-18 & 30:16-20. The Court has construed the term "adjacent" to mean "next to, but not above or beneath." Order Construing the Terms of U.S. Patent No. 6,827,901 ¶ 5 (Dec. 13, 2005) (D.I. 56).

On March 2, 2006, the Court granted Dako permission to file a summary judgment motion directed to the issue of whether or not the air mixer in the Artisan is "adjacent" to the reagent agitation zone. Hearing Tr. at 10 (Mar. 2, 2006) (D.I. 87). As explained below, there are disputed issues of fact for the jury to resolve. Accordingly, Ventana respectfully requests that the Court deny Dako's motion.

II. SUMMARY OF ARGUMENT

At several points during its normal operation, the Artisan's air mixer is positioned "adjacent" to the reagent agitation zone. The clear evidence of this infringing configuration is established by both Ventana and Dako witnesses. Therefore, there are disputed, material facts concerning Dako's mistaken assertion that the Artisan's air mixer is, "at all times," not adjacent to the reagent agitation zone.

Dako also asserts that its air mixer is not used for “directing a jet of air at the reagent agitation zone” or “inducing mixing in the reagent agitation zone” at certain times during its operation. This “method of operation” argument is both legally erroneous and factually disputed. Legally, Dako’s position is flawed because the apparatus claims of the ‘901 patent do not require a particular method of operation. Factually, Ventana’s expert Dr. Sharon disagrees with Dako’s assertions. He subjected those assertions to an empirical analysis and determined that the air jet was directed at the reagent agitation zone and that mixing was “clearly evident,” when the air mixer was adjacent to the reagent agitation zone. Dr. Sharon submitted video segments with his declaration to document this empirical analysis.

Finally, Dako does not contest the extensive testimony provided by Dr. Sharon that the Artisan’s air mixer is factually equivalent to the claimed air mixer of the ‘901 patent. Rather, Dako seeks to avoid infringement under the doctrine of equivalents by resort to certain legal limits on equivalence (prosecution history estoppel, claim vitiation, specific exclusion). As explained below, none of those legal limits apply in the present case.

III. STATEMENT OF FACTS

A. The ‘901 Patent

The asserted claims of the ‘901 patent are claims 1, 2, 3 and 45. *See* Sharon Report ¶ 10. Claims 1 and 45 are the independent claims.

The claimed invention is directed to an automated slide staining apparatus. It has a dual carousel arrangement, with a reagent carousel and a slide carousel. The reagent carousel dispenses reagents onto slides on the slide carousel arranged beneath the reagent carousel. It also includes an air mixer for mixing reagents in the reagent agitation zone.

See, e.g., Chang Ex. 1 at 24:52-25:18. The air mixer is the claim element at issue in Dako's motion.

The claimed air mixer includes two components: an air jet and an air supply means. *Id.* at 25:14. As this Court held, the air jet is "a stream of air," and the air supply means is "a device for supplying air, comprising the nozzle." Order ¶¶ 3-4 (Dec. 13, 2005) (D.I. 56). An exemplary embodiment of the air mixer is shown in Figure 16 of the '901 patent.¹ This figure shows nozzle 351 emitting an air jet 356 that impacts the reagent agitation zone on a slide. Chang Ex. 1 at 12:45-56. As a consequence of this arrangement, kinetic energy is transferred from the air jet to the reagents, resulting in mechanical agitation. Sharon Report ¶ 19.

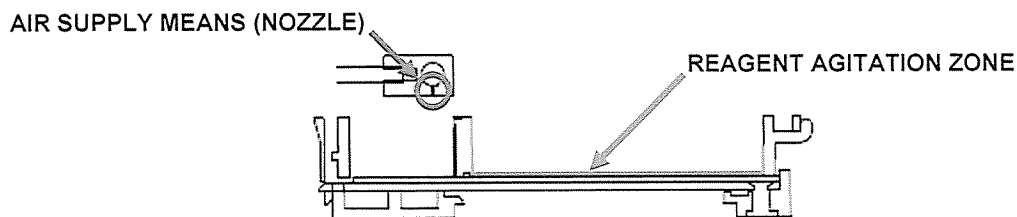
B. The Accused Artisan Device

The Artisan is an automated slide staining apparatus. It has a dual carousel arrangement, with a reagent carousel and a slide carousel. The reagent carousel dispenses reagents onto slides on the slide carousel arranged beneath the reagent carousel. It also includes an air mixer for mixing reagents in the reagent agitation zone. Zeliger Ex. B at 13; Sharon Report ¶¶ 12-16.

¹ The inventors also envisioned that the air mixer could be used to induce "vortex mixing." In vortex mixing, the nozzle of the air supply means is specially positioned in a manner to cause a swirling action in the reagent. Chang Ex. 1, Fig. 17. The vortex mixing configuration is the subject of claim 33 of the '901 patent. *Id.* at 28:8-11. Claim 33 has not been asserted in this litigation and is not part of this case. As a result, Dako's extensive discussion of vortex mixing (*see* Dako Br. at 4-5) is a red herring. The asserted claims 1, 2, 3 and 45 of the '901 patent do not require vortex mixing.

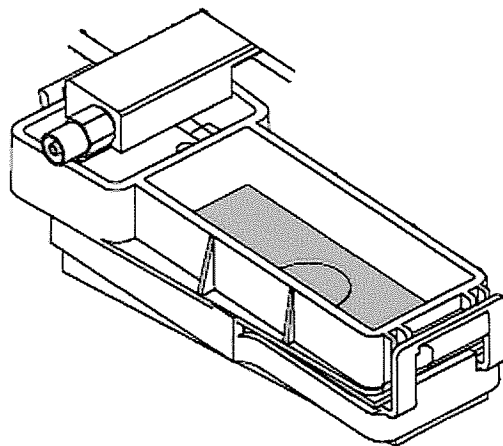
This Court expressly rejected Dako's vortex mixing argument. In Dako's opening *Markman* brief, it argued that the air mixer element of claims 1 and 45 include vortex mixers. Defendant DakoCytomation California Inc.'s *Markman* Brief at 18 (Oct. 17, 2005) (D.I. 43). The Court declined to adopt Dako's proposed construction. *See* Order ¶ 2 (Dec. 13, 2005) (D.I. 56).

The air mixer in the Artisan includes an air jet and a nozzle. The nozzle is an opening in the bottom surface of a plenum which is positioned near the slide. Sharon Report ¶ 16 (“The rectangular slit and the surrounding internal boundaries that define that slit within the plenum constitute the nozzle described in element [e] and defined by the Court’s claim construction.”). The nozzle is shown in the figure below:



To achieve mixing, the plenum discharges a stream of air from its nozzle. Sharon Report ¶ 16. The nozzle directs an oscillating air jet onto the slide that sweeps back and forth across the reagent agitation zone. *Id.*; Leon Decl. ¶ 16. During mixing, the air mixer makes one to five, and typically two to three passes across the reagent agitation zone. Chang Ex. 2 at 63:23-64:10. Air continues to flow from the air mixer during this entire process. *Id.* at 64:13-65:3; Glezer Report at 14.

At the beginning and end of each sweep (mixing cycle), the air mixer moves to a position next to, but not above or beneath the reagent agitation zone. Sharon Report ¶ 16; *see also* Glezer Report at 14 (“boundary situations”). The air mixer is also in a position that is next to, but not above or beneath the reagent agitation zone (shown in green) while it is in home position, as shown in the figure at right. Glezer Report at 10; *see also* Sharon Report ¶ 16.



IV. ARGUMENT

A. Legal Standards

On summary judgment, Dako must show that there is no genuine issue concerning any fact material to the question of patent infringement. Fed. R. Civ. P. 56(c). All reasonable inferences must be drawn in favor of Ventana, the nonmovant. *Karlin Tech. Inc. v. Surgical Devices, Inc.*, 177 F.3d 968, 970 (Fed. Cir. 1999).

Patent infringement requires a two-part analysis, in which the claims are first construed as a matter of law. *Id.* at 971. Second, the fact-finder must determine whether the claimed method is performed, either literally or under the doctrine of equivalents. *Id.* The comparison of the claims with the accused process is a question of fact. *Id.* at 974. “Infringement under the doctrine of equivalents requires an intensely factual inquiry.” *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1369 (Fed. Cir. 2001) (citation omitted). In order to prevail, Dako must show that no reasonable jury could conclude that the Artisan has the claimed air mixer, either literally or under the doctrine of equivalents. *Id.* at 1370.

B. The Artisan Literally Includes the Claimed “Air Mixer”

1. The Artisan’s Air Mixer is “Adjacent” to the Reagent Agitation Zone

Through its expert witness, Dr. Andre Sharon, Ventana set forth substantial evidence that the Artisan includes the claimed air mixer element in dispute,² including:

² Ventana also provided substantial evidence that the Artisan includes all other elements of the asserted claims. See Sharon Report ¶¶ 11-15 & 22-27. For these elements, Dako either concedes that they are present in the Artisan, or acknowledges that there are material facts in dispute. See Hearing Tr. at 2:13-3:10 & 5:14-19 (Mar. 2, 2006) (D.I. 87).

**Air mixer element
of claims 1 and 45****Evidence**

an air mixer comprising an air jet and an air supply means

“The Artisan has an air mixer which ‘directs an oscillating air jet onto the slide’ ... The rectangular slit and the surrounding internal boundaries that define that slit within the plenum constitute the nozzle [*i.e.*, air supply means] described in element [e] and defined by the Court’s claim construction.” Sharon Report ¶ 16.

positioned adjacent to [a] said reagent agitation zone

“When the plenum is in the home position and at the beginning and end of each mixing cycle, the nozzle and the air jet are next to, but not above or beneath the reagent agitation zone as defined by the Court.” Sharon Report ¶ 16.

for mixing reagents

“Q. In the Artisan the mixer uses air to mix the reagents, right? A. Correct.” Sharon Report ¶ 16 (quoting Dako’s Rule 30(b)(6) witness).

said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

“The Artisan has an air mixer which ‘directs an oscillating air jet onto the slide at the mixing station for agitating the contents of the slide. It consists of an air nozzle and a stepper motor for moving the nozzle and a stepper motor for moving the nozzle back and forth horizontally above the slide.’” Sharon Report ¶ 16.

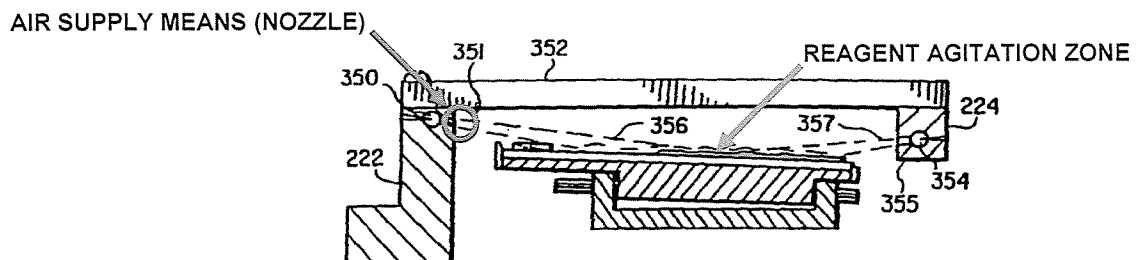
“The ‘air stream mixes and evenly distributes the reagents over the surface of the slide.’” Sharon Report ¶ 16.

At several points during its normal operation, the Artisan’s air mixer is positioned “adjacent” to the reagent agitation zone. The clear evidence of this infringing configuration is established by both Ventana and Dako witnesses. Ventana’s expert, Dr. Sharon, explained that as the plenum sweeps back and forth across the reagent agitation zone, the air mixer is next to, but not above or beneath the reagent agitation zone “at the beginning and end of each mixing cycle.” Sharon Report ¶ 16. It is also next to, but not above or beneath the reagent agitation zone in the home position. *Id.* Dako’s expert, Dr. Glezer, likewise illustrates the air mixer in these adjacent positions in his expert report. Glezer Report at 14.

In the face of this compelling evidence, Dako attempts to avoid literal infringement by proposing a distorted interpretation of the Court's construction of "adjacent." Dako asserts that the term "adjacent," as defined by the Court, prohibits the air mixer from having any vertical elevation when it is next to, but not above or beneath the reagent agitation zone. *See* Dako Br. at 14 ("the air mixer *is* still above the reagent agitation zone, albeit not directly above"). Dako is wrong.

First, this newly-minted interpretation of the term "adjacent" is at odds with Dako's own proposed claim construction in this case. In its *Markman* brief, Dako admitted that the intrinsic record shows that "sometimes one of the recited adjacent structures is slightly elevated." Dako *Markman* Br. at 19 (Oct. 17, 2005) (D.I. 43). In the face of this intrinsic evidence, Dako's proposed construction of "adjacent" was that "the structure that supplies the air and mixes the reagents cannot be *directly above* the sample." *Id.* at 20 (emphasis added); *see also id.* at 19 (structures are "never *directly above* or beneath the other" (emphasis added)).

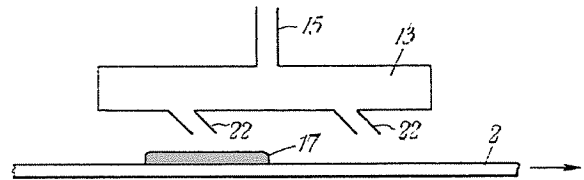
Second, Dako's new interpretation of "adjacent" is squarely inconsistent with the '901 patent itself. The inventors' preferred embodiment of the air mixer is shown in Figure 16 of the patent. The relevant portion of Figure 16 is reproduced below:



See Chang Ex. 1, Fig. 16 (labels added). In this preferred embodiment, the air mixer includes an air supply means (nozzle 351) that is next to, but not above or beneath the

reagent agitation zone (highlighted in green). As this figure shows, the air mixer is vertically elevated relative to the reagent agitation zone. Thus, Dako's new interpretation of the term "adjacent" would exclude the preferred embodiment.³ Such a narrow interpretation cannot be accepted because a claim construction that excludes the preferred embodiment is rarely, if ever, correct. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). After all, it would make no sense for an inventor to define the invention in a way that excludes the preferred embodiment, or for persons of skill in the art to read the patent in such a way. *Hoechst Celanese Corp. v. BP Chem. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996).

Third, Dako's new interpretation of "adjacent" is contradicted by its own expert, Dr. Manion. In attacking the validity of the '901 patent, Dr. Manion explained that the Gibbs prior art reference discloses the air mixer element of claims 1 and 45. *See Chang Ex. 3 at 15*. The air mixer is shown at right.



Chang Ex. 4, Fig. 4. In Gibbs, the sample is laterally moved so that the nozzle (jet needle 22) is sometimes above, and sometimes next to, pool 17 (highlighted in green), which corresponds to the reagent agitation zone. *Id.* at 3:37-53. As this figure shows, the nozzle is always vertically elevated relative to the reagent agitation zone. Yet, Dr. Manion provided sworn testimony that the air mixer of Gibbs "is at times next to, but not above or beneath the reagent agitation zone." *Chang Ex. 3 at 15*.

³ In fact, under Dako's interpretation, mixing would be impossible because there would be no way for the air jet to reach the reagent agitation zone located on the upper surface of the slide.

A jury is entitled to credit Ventana's evidence that the Artisan's air mixer is, at times, adjacent to (*i.e.*, next to, but not above or beneath) the reagent agitation zone. Dako cannot avoid infringement by claiming that the Artisan is only sometimes in a noninfringing configuration. *See Bell Commc 'ns Research, Inc. v. Vitalink Commc 'ns Corp.*, 55 F.3d 615, 622-23 (Fed. Cir. 1995).

**2. Dako Cannot Avoid Literal Infringement
Based On to the Artisan's Method of Operation**

For its next argument, Dako asserts that the Artisan's air mixer, when adjacent to the reagent agitation zone, does not operate in a manner to direct a jet of air at the reagent agitation zone or to induce mixing in the reagent agitation zone. Dako Br. at 15. Dako's argument is both legally erroneous and factually disputed.

Dako's legally erroneous claim construction. As a legal matter, Dako again attempts to distort the Court's claim construction to create a requirement that does not exist in the asserted claims. Dako does not deny that the Artisan has an air mixer; that its air mixer directs a jet of air at the reagent agitation zone; and that its air mixer induces mixing in the reagent agitation zone. Rather, Dako asserts that the claims require a method of operation where the steps of (i) directing a jet of air at the reagent agitation zone, and (ii) inducing mixing in the reagent agitation zone, are performed while the air mixer is positioned adjacent to the reagent agitation zone. *See* Dako Br. at 15. This assertion is meritless.

The asserted claims are apparatus claims. They cover an apparatus, and not a sequence of steps in a method. As the Federal Circuit has explained, "apparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) (emphasis in original); *see also In re*

Michlin, 256 F.2d 317, 320 (C.C.P.A. 1958) (“It is well settled that patentability of apparatus claims must depend upon structural limitations and not upon statements of function.”). Thus, the method of operation of a device is irrelevant to infringement of apparatus claims. Dako commits acts of infringement simply by making or selling the Artisan, regardless of whether it is used or how it is used. 35 U.S.C. § 271(a); *see also Catalina Mktg. Int’l, Inc. v. Coolsavings.com*, 289 F.3d 801, 809 (Fed. Cir. 2002) (“a patent grants the right to exclude others from making, using, selling, offering to sale, or importing the claimed apparatus or composition *for any use* of that apparatus or composition, whether or not the patentee envisioned such use”) (emphasis added); *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 995 (Fed. Cir. 2003). Consequently, there can be no requirement that the air mixer be used for directing the air jet or inducing mixing only at particular times during its operation. Such a requirement would impermissibly convert the ‘901 patent’s apparatus claims into method claims.

The material facts in dispute. Even under Dako’s flawed “method of operation interpretation, disputed material facts preclude summary judgment.

When the Artisan’s air mixer is adjacent to the reagent agitation zone “at the beginning and end of each mixing cycle” (Sharon Report ¶ 16), Dako asserts that “it is directing air at the wall of the slide clip, not at the reagent agitation zone.” Dako Br. at 16 (Dako refers to this as “boundary situations”). As alleged support for this assertion, Dako points to a drawing that purports to show an air jet with a “red arrow [that] represents the air curtain blown through the narrow slit in the plenum.” *Id.* at 17. Dako’s drawing proves nothing. Dr. Sharon explained that Dako’s red arrows are “inaccurate because the stream of air is not confined to the path shown by the red arrows

and it does not suddenly stop in the manner shown in the figures in Dako's brief."

Sharon Decl. ¶ 3. Instead, "the air jet diverges as it leaves the nozzle and also interacts with surrounding structures" which, as a consequence, "results in at least a portion of the air jet being directed at the reagent agitation zone" while the air mixer is located adjacent to the reagent agitation zone. *Id.*

Dako also relies on the assertion of Dr. Glezer that, while in an adjacent position, "the air mixer is directing air at the top of the slide clip" and that "the air mixer is then no longer directing air at the reagent agitation zone and therefore cannot induce mixing within the reagent agitation zone." Dako Br. at 17. These alleged facts are squarely disputed by Dr. Sharon. Sharon Decl. ¶ 3. Dr. Sharon explained that when the nozzle is positioned next to, but not above or beneath the reagent agitation zone, "at least a portion of the air jet is directed at the reagent agitation zone, even when the nozzle is above the wall of the slide clip."⁴ *Id.* ¶ 4.

⁴ Dako may argue that it is the combined effect of the nozzle and the slide clip (and not the nozzle alone) that directs the jet of air at the reagent agitation zone. Such an argument would fail. "It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device." *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999). The law has "never required that a claim read on the entirety of an accused device in order to infringe." *Id.* Nor is infringement avoided simply because an added element works in conjunction with the claimed element to achieve the claimed result. *Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1296-97 (Fed. Cir. 2000); *Vivid Techs., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 811-12 (Fed. Cir. 1999).

Dako's factual averments were also subjected to an empirical analysis (*id.* ¶ 5) and found to be wrong.⁵ Specifically, Dr. Sharon configured a plenum and slide clip assembly from the Artisan under conditions necessary to determine whether the Artisan's air mixer is used for directing a jet of air at the reagent agitation zone and inducing mixing in the reagent agitation zone. *Id.* ¶ 7. He positioned the air mixer adjacent to the reagent agitation zone, such that the entirety of the nozzle was located 0.1 mm (in a first configuration) and 1.0 mm (in a second configuration) outside of the reagent agitation zone. *Id.* ¶¶ 8-9. Using Dako's own published protocol for testing the mixer (*id.* ¶ 7), Dr. Sharon determined that "[m]ixing in the reagent agitation zone was clearly evident." *Id.* ¶ 8; *accord id.* ¶ 9. This empirical analysis was videotaped, and those video

⁵ In its brief (Dako Br. at 16 n.6), Dako suggests that it is "too late" for Ventana to respond to the arguments set forth in Dako's summary judgment motion. Dako is mistaken.

First, the factual basis for Ventana's infringement position was fully and timely set forth in the Sharon Report, served on January 31, 2006, within the time period provided for service of opening expert reports. Dr. Sharon articulated his opinion that the air mixer is "adjacent" to the reagent agitation zone when "in the home position and at the beginning and end of each mixing cycle." Sharon Report ¶ 16. He also explained that this "oscillating air jet" (*id.*) – which at times is next to, but not above or beneath the reagent agitation zone – is used for "agitating the contents of the slide." *Id.* Dr. Sharon's conclusions were not limited to the subset of time in which the air mixer is above the reagent agitation zone, nor were they limited to the subset of time in which the air mixer is next to, but not above or beneath the reagent agitation zone.

Second, the empirical analysis set forth in the Sharon Declaration was performed to rebut the factual assertions set forth in Dako's summary judgment brief and raised by Dako for the first time on February 9, 2006 (Summary judgment letter, D.I. 73), *after* expert reports were due and served. Even though Ventana had outstanding contention interrogatories directed to Dako's noninfringement contentions, and Dako provided supplemental responses to those interrogatories on January 30, 2006, those supplemental responses said nothing about its new "method of operation" theory of noninfringement presented in its summary judgment motion. *See* Chang Ex. 5 at 5-7. Ventana's expert was entitled to subject Dako's new, unsupported factual averments to an empirical analysis. As it turned out, these averments could not stand up to such scrutiny.

recordings are available for the Court to review. Sharon Decl. Ex. 2 (CD-ROM, files “First Configuration” and “Second Configuration”). These video segments dramatically demonstrate that the Artisan’s air mixer, when positioned adjacent to the reagent agitation zone, directs a jet of air at the reagent agitation zone and induces “clearly evident” mixing in the reagent agitation zone. *Id.* Dako’s conjecture of what “should be obvious from the pictures” of red arrows in its expert’s drawing (Dako Br. at 17) was empirically demonstrated to be nothing more than an incorrect supposition. Such evidence cannot support summary judgment.

**C. The Artisan Includes the Claimed “Air Mixer”
Under the Doctrine of Equivalents**

Ventana set forth a particularized analysis of how the Artisan performs substantially the same function of the air mixer element, in substantially the same way, to obtain substantially the same result. Sharon Report ¶¶ 17-20. Ventana also showed that at the time of infringement, the Artisan’s air mixer was known to be interchangeable with an air mixer that is positioned next to, but never above or beneath the reagent agitation zone. *Id.* ¶ 21. Dako makes no effort on summary judgment to challenge the factual basis for Ventana’s assertion of infringement under the doctrine of equivalents. Nor would Dako have a basis to do so, since the question of equivalency “requires an intensely factual inquiry” that normally must be resolved by the jury. *Toro*, 266 F.3d at 1369-70.

Instead of addressing the merits of Ventana’s doctrine of equivalents case, Dako’s summary judgment motion argues only that the doctrine of equivalents is limited by

certain legal doctrines. These arguments should be rejected for the reasons set forth below.⁶

1. Prosecution History Estoppel Does Not Apply

Dako argues that Ventana is estopped from asserting infringement under doctrine of equivalents based on certain arguments made in the prosecution history. Prosecution history estoppel (argument-based estoppel⁷) can be applied only if the alleged estoppel is shown to be “clear and unmistakable.” *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005).

Argument-based estoppel requires proof that the patentee surrendered specific *subject matter* during patent prosecution. *Id.* Estoppel does not apply in this case because the alleged estoppel relates to a different claim element and different subject matter. Here, the alleged surrender was made in reference to the position of adjacent *carousel structures* – and not the air mixer. The claim element at issue is the air mixer. It concerns the relative position of the “air mixer” compared to the “reagent agitation zone.” In contrast, the prosecution history passages that Dako relies upon for its “estoppel” argument concern the relative position of the “sample carousel” and the “reagent carousel.” Whatever those passages may suggest about the literal meaning of the word “adjacent,” they do not surrender a factually equivalent air mixer above a

⁶ Because these arguments are irrelevant to literal infringement, the Court should deny Dako’s motion without reaching these questions if it finds any disputed issues exist as to literal infringement.

⁷ There can be no amendment-based estoppel, because the “adjacent” requirement was not amended during prosecution. Rather, the “adjacent” requirement was part of the claims from the time they were initially submitted in a Preliminary Amendment. *See* Chang Ex. 6 at 2 (application claim 72).

reagent agitation zone – because those passages do not even discuss an air mixer or a reagent agitation zone.⁸

This Court apparently relied upon the patentees’ discussion of adjacent carousel structures to ascertain the literal meaning of the word “adjacent.” But the use of prosecution history in claim construction must not be conflated with its use for purposes of prosecution history estoppel. *See E.I. du Pont & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1438 (Fed. Cir. 1988). Statements that may be probative of the proper literal construction do not necessarily give rise to a clear and unmistakable surrender of equivalents. “The Court’s reliance upon the prosecution history for guidance in construing the patent claim, while finding the prosecution history insufficient to give rise to an estoppel, is consistent with the well-recognized distinction between the use of prosecution history in these two very different contexts.” *Mead Johnson & Co. v. Barr Labs., Inc.*, 38 F. Supp. 2d 289, 296 n.2 (S.D.N.Y. 1999).

Dako next relies upon *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570 (Fed. Cir. 1995), for its prosecution history estoppel argument. Under *Southwall*, “once an argument is made regarding a claim term so as to create an estoppel, the estoppel will apply to that term in other claims.” *Id.* at 1584. *Southwall* is inapplicable for two fundamental reasons.

⁸ *See* Zeliger Ex. A at 13-15 & 20; Dako Br. at 18. In these passages, the patentees distinguished the claimed “sample carousel arranged beneath said reagent carousel” from the prior art, on the basis that in the prior art the sample carousels “are adjacent to and not below the reagent carousel.” Zeliger Ex. A at 15. Dako’s attempt to indiscriminately apply estoppel is nonsensical on its face, because the ‘901 patent uses the word “adjacent” in a variety of very different contexts. Elsewhere in the intrinsic record, the term “adjacent” is also used to describe certain structures that are above and below one another. *See* Chang Ex. 1 at 7:24-31 & Fig. 2 (splash guard 50 extends upward “to a position *adjacent* the upper plate 8,” shown as directly above splash guard 50).

First, the patentee's statements in the prosecution history at issue here did not "create an estoppel." As explained above, simply because the prosecution history is consulted for definitional assistance does not mean that an estoppel is created to bar infringement under the doctrine of equivalents. Second, the prosecution history statements relied upon by Dako related to the claim term "beneath," *not* the claim term "adjacent." See Zeligier Ex. A at 13-15 & 20. Because no other use of the term "adjacent" in the claims is at issue, estoppel cannot be applied under *Southwall*.

2. Infringement Under the Doctrine of Equivalents Does Not Vitate the Air Mixer Claim Element

On the theory that positioning of the Artisan's air mixer directly above the reagent agitation zone avoids literal infringement (which Ventana disputes), Dako argues that infringement under the doctrine of equivalents would vitiate the "adjacent" requirement. Dako misapplies the principle of claim vitiation.

Infringement under the doctrine of equivalents necessarily assumes that there is no literal infringement. Therefore, the mere absence of an "adjacent" air mixer cannot give rise to claim vitiation; otherwise, the exception (claim vitiation) would swallow the rule (doctrine of equivalents). Rather, the Court must consider the totality of circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless. *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1379-80 (Fed. Cir. 2005).

The Artisan can infringe the asserted claims without rendering the "adjacent" language meaningless. Dr. Sharon explained (Sharon Report ¶ 21):

The goal of mixing is to increase the uniformity of the reagent solution and to agitate the reagents relative to the sample. An engineer designing such a system in 2004⁹ would know that this can be accomplished with a moving, vertical air jet that originates from above or with an angled air jet that originates from the side. Both air mixers transfer kinetic energy from the air jet to the reagents, achieving the above goal.

In the Artisan, the air mixer is adjacent to the reagent agitation zone for at least a portion of the mixing cycle. Sharon Report ¶ 16. Regardless of whether that is sufficient to demonstrate literal infringement, it certainly demonstrates that any difference is in degree, and is not a difference in kind. For this reason, the authority upon which Dako relies does not apply. *See, e.g., Fin Control Sys. PTY, Ltd. v. OAM, Inc.*, 265 F.3d 1311, 1320 (Fed. Cir. 2001) (accused surfboard's screws engaged the fin's tabs from the "front" would vitiate the claim language that the screws engage the "side wall" of the tabs "laterally").

More pertinent is *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309 (Fed. Cir. 1998). In *Ethicon*, claim 24 required a restraining structure that contacts the barrier "*during* staple firing." *Id.* at 1321 (emphasis added). Similarly, Dako asserts that the '901 patent should be understood to require directing the air jet and inducing mixing *during* the time the air mixer is adjacent. In *Ethicon*, the accused device "loses contact with the barrier *just prior to* staple firing." *Id.* (emphasis added). In the Artisan, Dako claims that the accused device ceases directing the air jet and inducing mixing in the "boundary situations" (Dako Br. at 16-17) which occur when the air mixer is moved

⁹ Equivalence is determined as of the time of infringement, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997), which in the present case began in 2004.

“just barely outside the left and right boundaries” of the reagent agitation zone. Glezer Report at 14 (emphasis added). There is infringement under the doctrine of equivalents in these circumstances, because such “subtle difference in degree” does not give rise to claim vitiation. *Ethicon*, 149 F.3d at 1321; *see also Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997) (accused surgical rod that extended to the isthmus did not vitiate claim element that required the rod to “extend through” the isthmus).

3. The Specific Exclusion Principle Is Inapplicable to the Air Mixer Element

Dako’s final attempt to defeat infringement under the doctrine of equivalents is based on the specific exclusion principle. As with Dako’s other two purported legal limits on the doctrine of equivalents, this argument fails.

The specific exclusion principle was described by the Federal Circuit:

[A]ny analysis of infringement under the doctrine of equivalents *necessarily* deals with subject matter that is “beyond,” “ignored” by, and not included in the literal scope of a claim. Such subject matter is not necessarily “specifically excluded” from coverage under the doctrine unless its inclusion is somehow inconsistent with the language of the claim. Literal failure to meet a claim limitation does not necessarily amount to “specific exclusion.”

Ethicon, 149 F.3d at 1317 (emphasis in original). In the present case, the Court concluded that a position “above” the reagent agitation zone is not included in the literal scope of the term “adjacent.” Order ¶ 5 (Dec. 13, 2005) (D.I. 56). As with *Ethicon*, literal failure to meet an “adjacent” position does not necessarily amount to “specific exclusion.” Rather, Dako must demonstrate that these two positions are so fundamentally inconsistent that they cannot be considered equivalent. Not only is Dako’s brief utterly

devoid of any such proof, but Dr. Sharon's analysis demonstrates that these positional configurations were known to be interchangeable, Sharon Report ¶ 21, and operate in substantially the same way since the air mixer can transfer kinetic energy from the air jet to the reagents in both positions. *Id.* ¶ 19.

Because the claim language contains nothing that remotely resembles a "specific exclusion," Dako instead points to the language of this Court's claim construction order; *i.e.*, Dako asserts that when the Court defined "adjacent" as "next to, but not above or beneath," the claim construction triggered the specific exclusion principle. This reasoning was expressly considered and rejected in *ACLARA BioSciences, Inc. v. Caliper Techs. Corp.*, No. C99-1968 CRB, 2000 WL 1639507 (N.D. Cal. Oct. 27, 2000) (attached as Chang Ex. 7). In that case, the term "trench" was at issue. The court literally construed "trench" to be an *uncovered* structure. *Id.* at *10. The defendant asserted the specific exclusion principle and argued that a *covered* structure could not infringe under the doctrine of equivalents. *ACLARA* held that a court's claim construction does not invoke the specific exclusion principle:

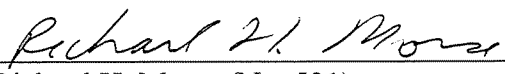
[T]he fact that this Court in its Markman Order interpreted the term "trench" to mean an uncovered structure does not mean that some other structure could not perform substantially the same function in substantially the same way to obtain substantially the same result and therefore be equivalent.... The Court's definition of the term "trench" in its Markman Order established that the LabChips do not *contain* a trench for the purposes of literal infringement, but the Court's claim construction does not foreclose the possibility that a covered structure might be *equivalent* to a trench for purposes of infringement under the doctrine of equivalents.

Id. at *13-14 (emphasis in original). Because the doctrine of equivalents is available in the present case, the jury is entitled to resolve the “intensely factual” issue of equivalence.

V. CONCLUSION

For the foregoing reasons, Ventana respectfully requests that the Court deny Dako’s summary judgment motion.

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DATED: March 30, 2006

CERTIFICATE OF SERVICE

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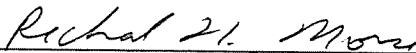
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